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Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) No 2016/429): low pathogenic avian influenza

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Abstract

Low pathogenic avian influenza (LPAI) has been assessed according to the criteria of the Animal Health Law (AHL), in particular criteria of Article 7 on disease profile and impacts, Article 5 on the eligibility of LPAI to be listed, Article 9 for the categorisation of LPAI according to disease prevention and control rules as in Annex IV and Article 8 on the list of animal species related to LPAI. The assessment has been performed following a methodology composed of information collection and compilation, expert judgement on each criterion at individual and, if no consensus was reached before, also at collective levels. The output is composed of the categorical answer, and for the questions where no consensus was reached, the different supporting views are reported. Details on the methodology used for this assessment are explained in a separate opinion. According to the assessment performed, LPAI can be considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL. The disease would comply with the criteria as in Sections 3 and 5 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in points (c) and (e) of Article 9(1). The animal species to be listed for LPAI according to Article 8(3) criteria are all species of domestic poultry and wild species of mainly Anseriformes and Charadriiformes, as indicated in the present opinion.

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Keywords: avian influenza, LPAI, Animal Health Law, listing, categorisation, impact

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

The background and Terms of Reference (ToR) as provided by the European Commission for the present document are reported in section 1.2 of the scientific opinion on the ad hoc methodology followed for the assessment of the disease to be listed and categorised according to the criteria of Article 5, Annex IV according to Article 9 and Article 8 within the Animal Health Law (AHL) framework (EFSA AHAW Panel, 2017b).

1.2. Interpretation of the Terms of Reference

The interpretation of the ToR is as in section 1.2 of the scientific opinion on the ad hoc methodology followed for the assessment of the disease to be listed and categorised according to the criteria of Article 5, Annex IV according to Article 9 and Article 8 within the AHL framework (EFSA AHAW Panel, 2017b).

The present document reports the results of assessment on low pathogenic avian influenza (LPAI) according to the criteria of the AHL articles as follows:

- Article 7: Low Pathogenic Avian Influenza profile and impacts
- Article 5: eligibility of Low Pathogenic Avian Influenza to be listed
- Article 9: categorisation of Low Pathogenic Avian Influenza according to disease prevention and control rules as in Annex IV
- Article 8: list of animal species related to Low Pathogenic Avian Influenza

2. Data and Methodologies

The methodology applied in this opinion is described in detail in a dedicated document about the ad hoc method developed for assessing any animal disease for the listing and categorisation of diseases within the AHL framework (EFSA AHAW Panel, 2017b).

3. Assessment

3.1. Assessment according to Article 7 criteria

This section presents the assessment of LPAI according to the Article 7 criteria of the AHL and related parameters [see Table 2 of the opinion on methodology (EFSA AHAW Panel, 2017b)], based on the information contained in the factsheet as drafted by the selected disease scientist (see section 2.1 of the scientific opinion on the ad hoc methodology) and amended by the AHAW Panel.

3.1.1. Article 7(a) disease profile

The assessment focuses on H5 and H7 LPAI viruses (LPAIV) since they are internationally notifiable and subject to legislative control (Directive 94/2005/EC¹). The rationale for legislative control and surveillance of H5/H7 LPAIV is to ensure effective control before they may mutate to highly pathogenic avian influenza (HPAI) virus (HPAIV), which could have more severe consequences for veterinary public health. In gathering evidence for the factsheet, some supporting material has been utilised, based on biological findings of other LPAIV (subtypes other than H5/H7) which have common ecology and biology.

3.1.1.1. Article 7(a)(i) Animal species concerned by the disease

Susceptible animal species

Parameter 1 – Naturally susceptible wildlife species (or family/orders)

Mainly Anseriformes and Charadriiformes (Daoust et al., 2011; Kuiken, 2013) have been reported as LPAI-infected wild bird species (see Table 1). HPAIV have been detected in over a hundred species of wild birds from at least 13 different orders (EFSA, 2006; EFSA AHAW Panel, 2017a). The LPAI susceptibility of many wild bird species has not been assessed.

¹ Directive 2005/94/EC of the European Parliament and of the Council of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC. OJ L 10, 14.1.2006, p. 16–65.

Table 1: LPAIV-infected wild birds (based on Kuiken (2013) and Duncan et al. (2017); EMPRES-I, online 2007–2017 data)

Common name (Latin name)	Family	Order
Ruddy turnstone (<i>Arenaria interpres</i>), common snipe (<i>Gallinago gallinago</i>)	Scolopacidae	Charadriiformes
Laughing gull (<i>Leucophaeus atricilla</i>), ring-billed gull (<i>Larus delawarensis</i>), black-headed gull (<i>Larus ridibundus</i>), herring gull (<i>Larus argentatus</i>), great black-backed gull (<i>Larus marinus</i>)	Laridae	Charadriiformes
Pied avocet (<i>Recurvirostra avosetta</i>)	Recurvirostridae	Charadriiformes
mute swan (<i>Cygnus olor</i>), mallard (<i>Anas platyrhynchos</i>), northern pintail (<i>Anas acuta</i>), northern shoveler (<i>Anas clypeata</i>), Canada goose (<i>Branta canadensis</i>), tundra swan (<i>Cygnus columbianus</i>), Redhead (<i>Anas americana</i>), wood duck (<i>Anas sponsa</i>), greater white-fronted goose (<i>Anas albifrons</i>), common teal (<i>Anas crecca</i>), Eurasian wigeon (<i>Anas penelope</i>), garganey (<i>Anas querquedula</i>), gadwall (<i>Anas strepera</i>), greylag goose (<i>Anser anser</i>), lesser white-fronted goose (<i>Anser erythropus</i>), bean goose (<i>Anser fabalis</i>), common pochard (<i>Aythya ferina</i>), tufted duck (<i>Aythya fuligula</i>), ashy-headed goose (<i>Chloephaga poliocephala</i>), whooper swan (<i>Cygnus cygnus</i>), harlequin duck (<i>Histrionicus histrionicus</i>), ruddy duck (<i>Oxyura jamaicensis</i>), common shelduck (<i>Tadorna tadorna</i>)	Anatidae	Anseriformes
Common coot (<i>Fulica atra</i>)	Rallidae	Gruiformes
Black-crowned night heron (<i>Nycticorax nycticorax</i>)	Ardeidae	Pelecaniformes
Great cormorant (<i>Phalacrocorax carbo</i>)	Phalacrocoracidae	Suliformes

LPAIV: low pathogenic avian influenza virus; EMPRES-I: Global Animal Diseases Information System, Food Agriculture Organisation.

Parameter 2 – Naturally susceptible domestic species (or family/orders)

All species of domestic poultry, to include the family Phasianidae (chickens, turkeys and related poultry such as quail and pheasant), Odontophoridae (quail), Numidae (guinea fowl) and Struthionidae (ostriches) and also other birds native and introduced such as farmed Anseriformes, particularly including ducks, geese and ratites are susceptible (Table 2). In general, viruses from birds rarely infect mammals (reviewed in Swayne, 2016).

Table 2: Main domestic bird families susceptible to LPAIV

Common name	Family	Order
Chicken, turkey, quail (Old World species), pheasant	Phasianidae	Galliformes
Quail (New World species)	Odontophoridae	Galliformes
Guinea fowl	Numididae	Galliformes
Duck, geese	Anatidae	Anseriformes
Ostrich, ratites ^(a)	Struthionidae	Struthioniformes

LPAIV: low pathogenic avian influenza virus.

(a): Sometimes classified as a diverse group of large, flightless birds of the infraclass Palaeognathae.

Parameter 3 – Experimentally susceptible wildlife species (or family/orders)

There is no additional information (see Table 1).

Parameter 4 – Experimentally susceptible domestic species (or family/orders)

Pigs, mustelid, horses, domestic carnivores (cats and dogs), seals and other sea mammals, rats, rabbits, guinea pigs, mice and non-human primates have been infected experimentally (Short et al., 2015) (Table 3).

Table 3: Main domestic families/orders susceptible to LPAIV

Common name	Family	Order
Pig	Suidae	Artiodactyla
Horse	Equidae	Perissodactyla
Dog	Canidae	Carnivora
Cat	Felidae	Carnivora
Mustelid	Mustelidae	Carnivora
Seals and other sea mammals	Enaliarctidae	Carnivora
Rat, mouse	Muridae	Rodentia
Guinea pig	Caviidae	Rodentia
Non-human primates	Several	Primates

LPAIV: low pathogenic avian influenza viruses.

Reservoir animal species

Parameter 5 – Wild reservoir species (or family/orders)

Wild water birds, in particular Anseriformes and Charadriiformes (Daoust et al., 2011; Kuiken, 2013; Verhagen et al., 2014), are considered the main reservoir of LPAIV.

Parameter 6 – Domestic reservoir species (or family/orders)

No domestic species are reported as natural reservoirs and these become infected normally via spillover from wild bird reservoir species (Swayne, 2016). In some ecosystems or situations (e.g. wild bird markets, duck paddy field systems), domestic ducks (Anseriformes) may maintain virus for long periods. Also, domestic water bird populations (Anseriformes) could become reservoir.

3.1.1.2. Article 7(a)(ii) The morbidity and mortality rates of the disease in animal populations

Morbidity

Parameter 1 – Prevalence/Incidence

EU Member States (MS) perform annual surveillance programmes in poultry, mainly using a risk-based sampling approach. Table 4 indicates that the proportion of seropositive holdings was between 0.15% and 0.25% in the period 2010–2014. Positive samples were reported in 8–11 MS. Comparing MS or poultry categories is not possible due to large variations in the number of samples per country and per poultry category.

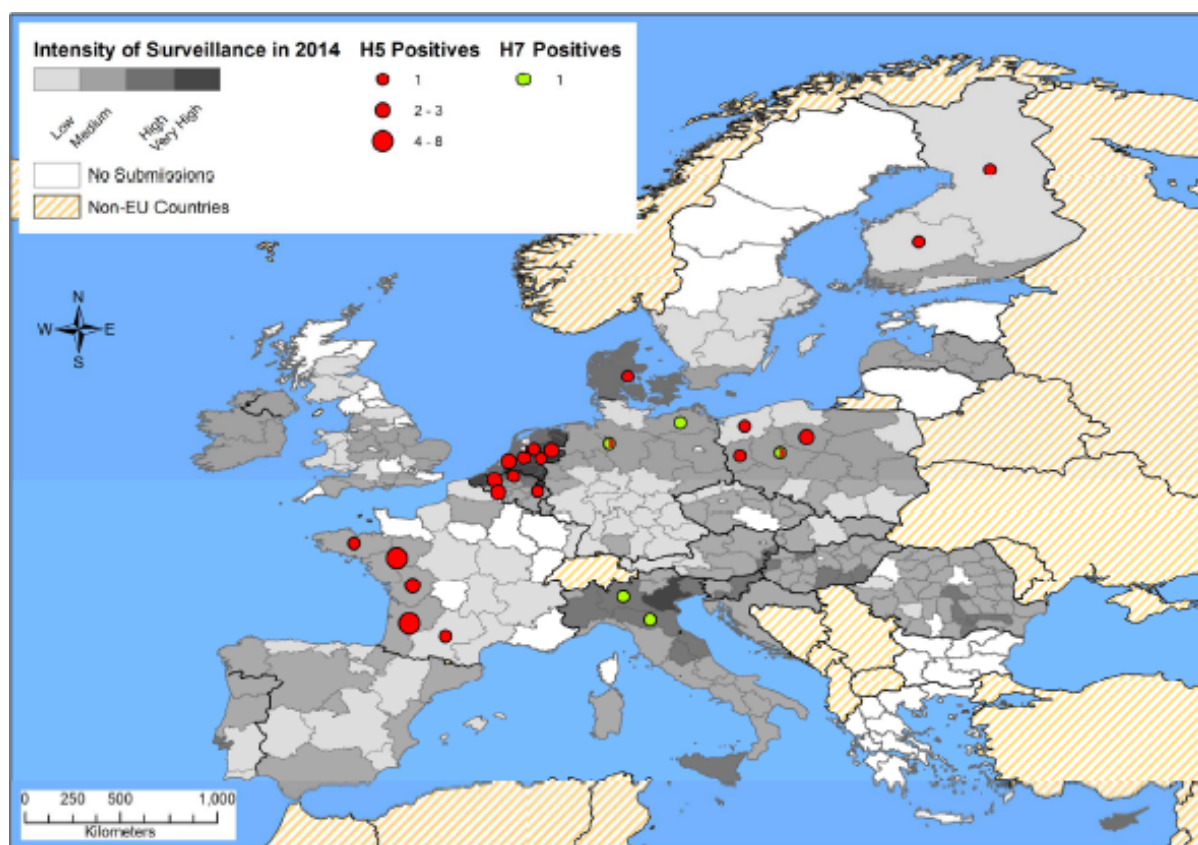
Table 4: LPAI serosurveillance data in number of holdings (%) (based on Annual EU surveillance reports)

Category	Year				
	2010	2011	2012	2013	2014
Holdings sampled	29,484	29,806	29,404	25,220	19,813
H5 positive holdings	50	50	40	57	38
H7 positive holdings	14	15	4	6	5
Number Member States positive	8	10	9	11	8
Poultry category					
Chicken breeders				1	2
Laying hens	4	4	4	1	4
Free range laying hens	1	1	3	7	4
Broilers					
Fattening turkeys			1		
Turkey breeders					
Fattening ducks		6	7	8	11

Category	Year				
	2010	2011	2012	2013	2014
Breeder ducks	4	25	21	27	7
Fattening geese	22	2	1	1	2
Breeder geese	8	8	4	5	10
Backyard	4	8	1	3	
Farmed game birds	15	3	1	2	
Ratites					1
Other	5	6		7	2

LPAI: low pathogenic avian influenza.

LPAI has been detected in wild birds across the year and in several MS (Barral et al., 2008; Busquets et al., 2010; Perez-Ramirez et al., 2010, 2012; Jurado-Tarifa et al., 2014; Latorre-Margalef et al., 2014; Swieton et al., 2017). Furthermore, the maps in Figure 1 show that some regions had seropositive holdings in 2014 and 2015. This was, for instance, the case in south-west France, where new highly pathogenic H5 viruses emerged during winter 2015/16, which were never identified in wild birds before (Briand et al., 2017).



The classification of the intensity of surveillance is grouped by holdings sampled per 100 km² Low: up to 10, medium: 11–100, high: 101–500, very high: > 500

Figure 1: Map of the intensity of sampling in the EU AI poultry survey and holdings testing serologically positive for H5 and H7 in 2014 and 2015 [taken from APHA (2015, 2016)]

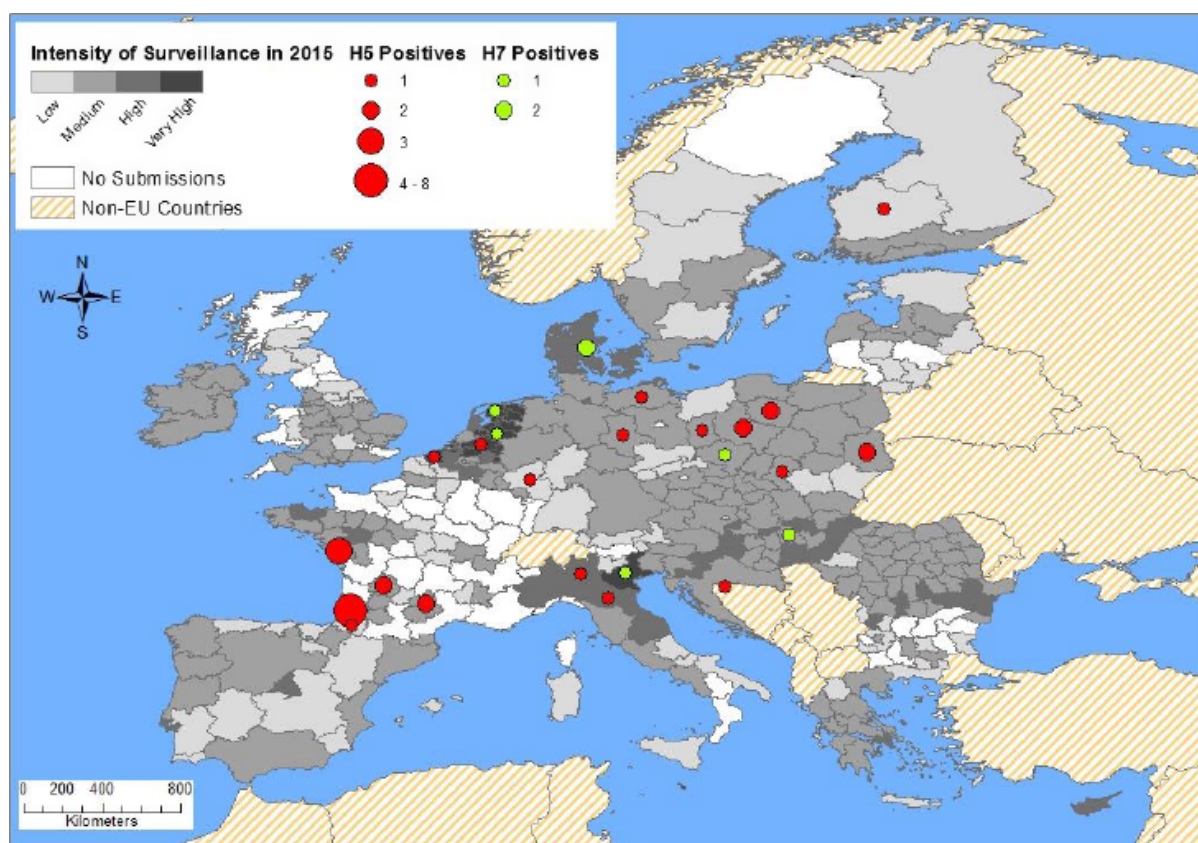


Figure 1: (Continued)

In the period 2007–2017, LPAI outbreaks were reported in 321 holdings located in 14 MS (Table 5). The seroprevalence data and the outbreak data clearly show that LPAIV circulate every year in multiple MS and mainly in ducks, geese and game birds.

Table 5: LPAI outbreaks within the EU (reported in ADNS between 1/1/ 2007 and 31/12/2016)

Country	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	Grand total
Germany	0	32	6	3	23	3	10	2	3	10	92
France	0	0	3	1	0	0	0	0	14	28	46
Italy	18	3	37	9	23	16	9	5	8	4	132
Netherlands	0	0	0	1	5	2	6	2	3	2	21
Belgium	0	2	0	0	0	0	0	0	0	0	2
United Kingdom	2	0	0	0	0	0	0	0	1	1	4
Ireland	0	0	0	0	0	1	0	0	0	0	1
Denmark	0	1	0	2	0	0	1	0	0	2	6
Spain	0	0	1	0	0	0	1	0	0	0	2
Portugal	4	0	0	0	0	0	0	0	0	0	4
Norway	0	1	0	0	0	0	0	0	0	0	1
Czech Republic	0	0	2	0	0	0	0	0	0	0	2
Bulgaria	0	0	0	0	6	0	0	0	0	0	6
Romania	0	0	1	1	0	0	0	0	0	0	2
Grand total	24	39	50	17	57	22	27	9	29	47	321

LPAI: low pathogenic avian influenza; ADNS: Animal Disease Notification System.

Parameter 2 – Case morbidity rate (% clinically diseased animals out of infected ones)

Morbidity of LPAI can be variable depending on the virus strain and poultry species. In ducks, morbidity can be very low with subclinical infection due to localised enteric infection, whereas in chicken layers it may be higher but influenced, for instance, by flock size and density (Gonzales et al., 2012a).

Mortality

Parameter 3 – Case fatality rate

In general, mortality due to LPAI is usually less than 5% in most avian species unless exacerbated by secondary pathogens. Localised infection is normal, it remains enteric and respiratory (Swayne et al., 2013).

3.1.1.3. Article 7(a)(iii) The zoonotic character of the disease

Presence

Parameter 1 – Report of zoonotic human cases (anywhere)

Humans can be infected with LPAIV such as H7N9. Rare mild zoonotic cases have been reported principally with conjunctivitis and mild respiratory infection in humans occupationally exposed. The number of reported H7N9 human cases worldwide in the period 2007–2016 is 1,157 (based on EMPRES-I, online), of which two cases in the America and all the others in Asia. The majority of the H7N9 human cases have been associated with direct or indirect contact with infected live or dead poultry. There is no scientific evidence suggesting efficient transmission of these viruses between persons.

3.1.1.4. Article 7(a)(iv) The resistance to treatments, including antimicrobial resistance

Parameter 1 – Resistant strain to any treatment even at laboratory level

Amantadine resistance has been described in poultry in China and Egypt (Cheng et al., 2009; Zaraket et al., 2010; CDC, 2017). A H7N9 virus isolated from a human case has been reported (ECDC, online) to contain a mutation in the neuraminidase protein relevant for antiviral resistance against oseltamivir and zanamivir.

3.1.1.5. Article 7(a)(v) The persistence of the disease in an animal population or the environment

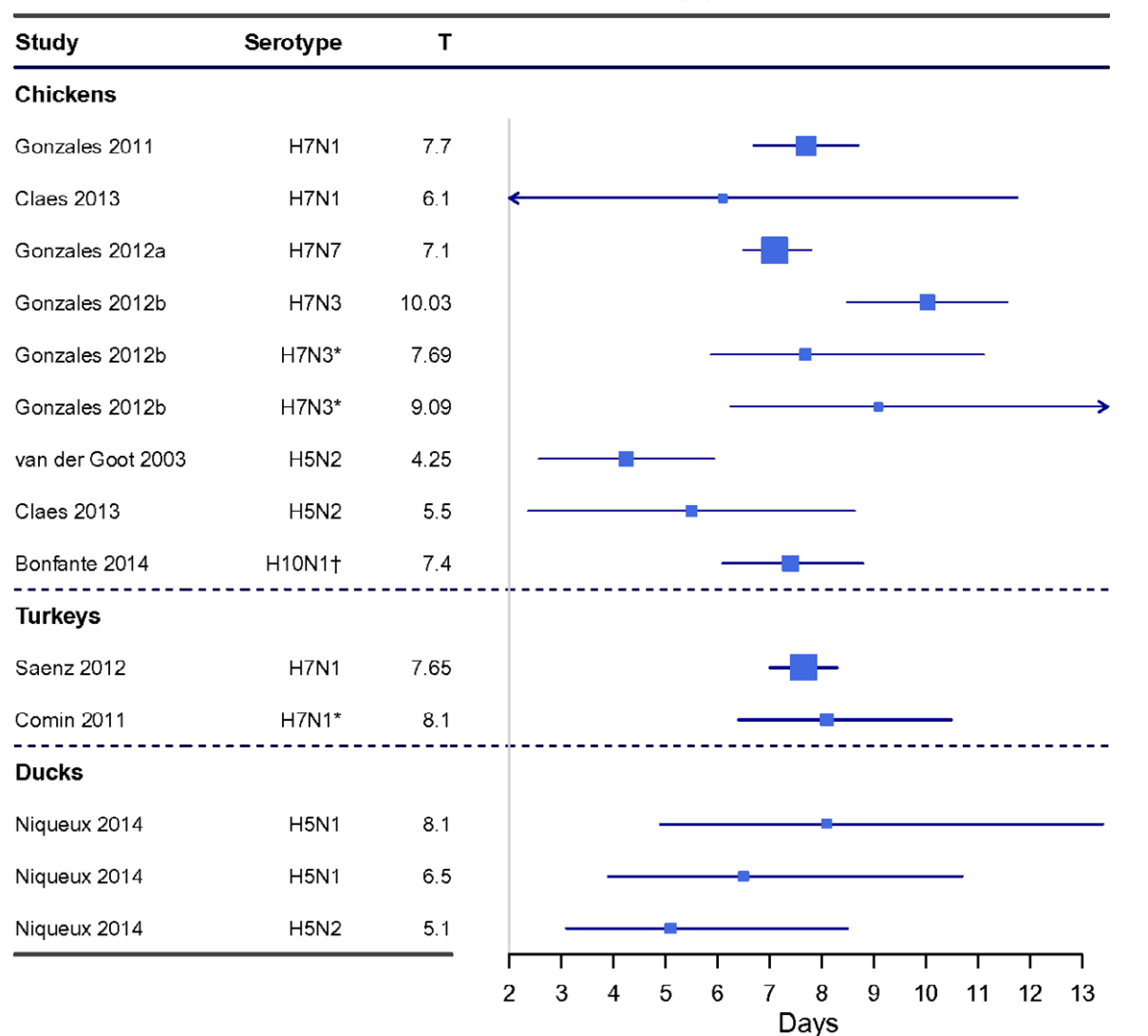
Animal population

Parameter 1 – Duration of infectious period in animals

The mean infectious period in individuals is 4–10, 7–8 and 5–8 days in chickens, turkeys and ducks, respectively (Table 6).

Table 6: LPAI infectious period in poultry (in days) (data received as per procurement, Erasmus University Medical Centre, OC/EFSA/ALPHA2015/01, unpublished)

Infectious period (T)



LPAI: low pathogenic avian influenza.

T = mean value of infectious period in days (mean, 95% lower confidence limit and 95% upper confidence limit)

Parameter 2 – Presence and duration of latent infection period

Animal latent period up to 3 days depending on virus strain, infecting dose and species have been reported; flock level latency ranges 14 days (Swayne and Halvorson, 2008).

Parameter 3 – Presence and duration of the pathogen in healthy carriers

LPAIV infections may go unreported for some time (Marche et al., 2014). By definition most populations are mildly affected (Daoust et al., 2013). In extreme circumstances, shedding in individual birds has been recorded for up to 3–4 weeks in chickens, ducks and turkeys (Brown et al., 2012).

Environment

Parameter 4 – Length of survival (dpi) of the agent and/or detection of DNA in selected matrices (soil, water, air) from the environment (scenarios: high and low T)

Survivability will depend on the virus strain and the substrate together with temperature, humidity and pH. For example, at 4°C, the maximum resistance time varied between 18 and 176 days for 12 LPAIV of different H types (Brown et al., 2009). In general, viruses were most stable at slightly basic pH (7.4–8.2), low temperatures (< 17°C) and fresh to brackish salinities. In faeces, 35 days at 4°C and

7 days at 20°C; in water, up to 158 days at 17°C, whereas in manure and litter, 2–7 days; rapidly inactivated in air less than 1 day due to desiccation (Keeler et al., 2012), low pH (< 5.0) or salinity (EFSA, 2008; Swayne and Halvorson, 2008; Reis et al., 2012).

3.1.1.6. Article 7(a)(vi) The routes and speed of transmission of the disease between animals, and, when relevant, between animals and humans

Routes of transmission

Parameter 1 – Types of routes of transmission from animal to animal (horizontal, vertical)

A comparison of the different transmission routes is provided in Table 7. Although differences between isolates have been observed, results from Pillai et al. (2010) indicate that a poultry derived isolate transmits better between chickens than a wild bird derived isolate. Wild bird isolates transmit better among turkeys and ducks than among chickens. Once the virus is adapted to a species, it can spread easily within flocks. Infectious excretions are considered the most important source of virus transmission between animals. Therefore, contaminated fomites are an important entry route for the virus into poultry houses. Transmission of the virus via direct contact is considered less important than via indirect contacts, both for domestic and wild birds. Vertical transmission has not been observed.

Table 7: LPAI transmission routes (Pantin-Jackwood et al., 2012; Claes et al., 2013, 2014)

Mode	Chicken	Turkey	Duck
Horizontal intraspecies	+++	+++	+++
Vertical	–	–	–
Fomite	++	++	++
Wild bird origin	+	++	+++
Horizontal interspecies	+	++	++

+++ : highly efficient; ++ : effective; + : can occur, but low efficiency; – : not reported.

Parameter 2 – Types of routes of transmission between animals and humans (direct, indirect, including foodborne)

Transmission is by direct exposure to aerosolised droplet materials in poultry environment through the conjunctiva or the upper respiratory tract. Food is not considered a route of avian influenza virus transmission to humans since acidic pH in the stomach and bile salts in the duodenum reduce the virus infectivity (EFSA BIOHAZ Panel, 2010).

Speed of transmission

Parameter 3 – Incidence between animals and, when relevant, between animals and humans

Interspecies transmission can occur with high probability between animals of the same taxonomic family such as chickens and turkeys (Pillai et al., 2010; Mughini-Gras et al., 2014); interspecies transmission across different orders, such as duck to turkey is less likely (Mughini-Gras et al., 2014; Claes et al., 2015) with even greater reduced efficiency between species of different classes, i.e. avian to human.

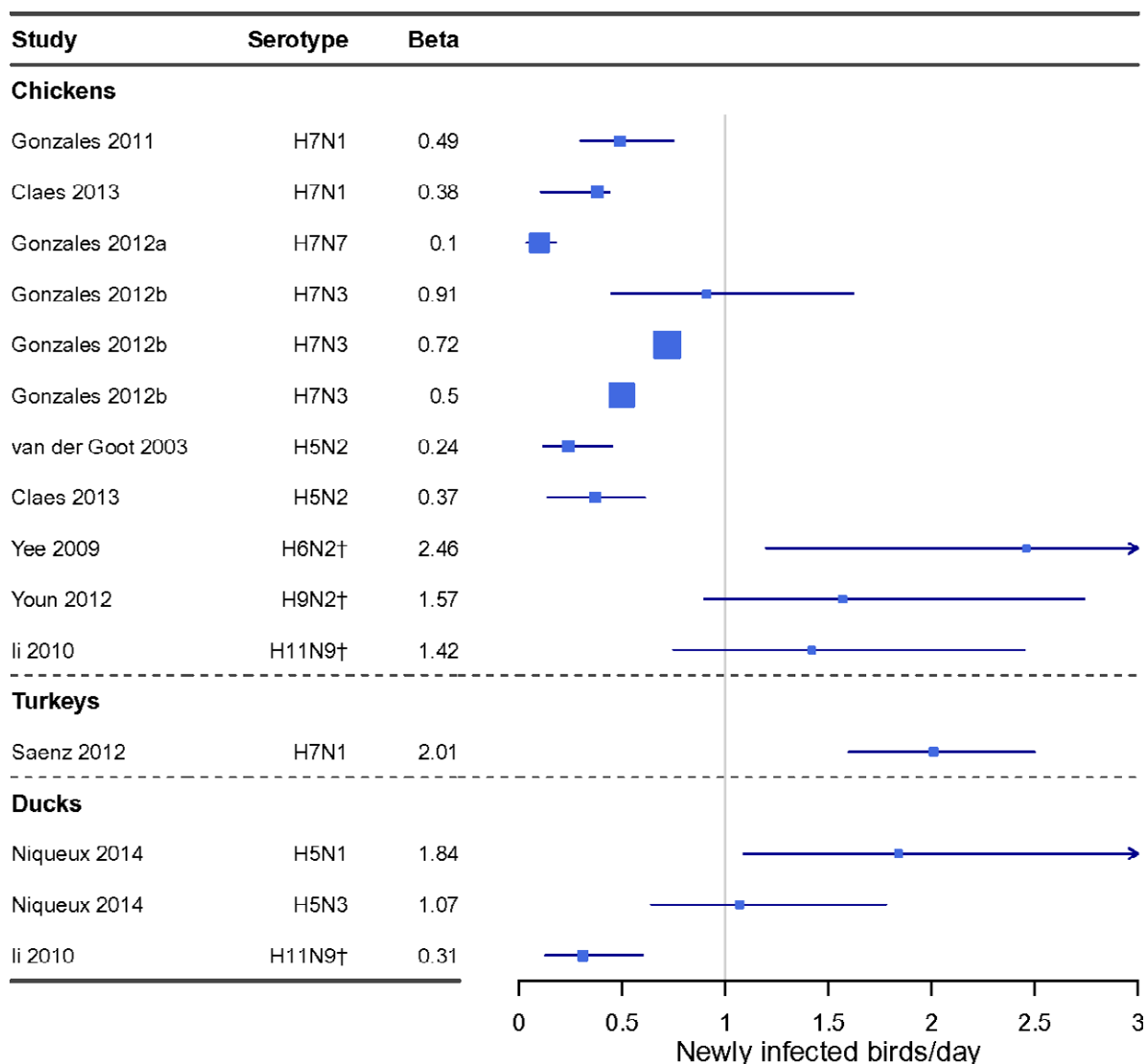
Parameter 4 – Transmission rate (beta) (from R_0 and infectious period) between animals and, when relevant, between animals and humans

In chicken, the basic reproduction ratio, R_0 (the average number of secondary infections caused by one infectious bird introduced in a fully susceptible population), for LPAI ranges 0.8–9.1 (data received as per procurement, Erasmus University Medical Centre, OC/EFSA/ALPHA2015/01, unpublished). The average infectious period of LPAI (Table 6) is considerably longer than that of HPAI, resulting in an transmission rate parameter, β (the average number of secondary cases caused by one infectious individual per day) at lower ranges for LPAI than for HPAI (0.1–2.46 and 0.76–4.5 respectively).

For turkeys, less information is available than for chicken, however, the trend appears similar to that of chicken. Also, for ducks the information is limited, although it points towards higher transmission parameters of LPAIV in ducks than in chickens (Table 8).

Table 8: LPAI transmission rates (beta) between animals for viruses isolated from poultry (data received as per procurement, Erasmus University Medical Centre, OC/EFSA/ALPHA2015/01, unpublished)

LPAI Transmission rates – Virus isolated from poultry



LPAI: low pathogenic avian influenza.

Mean, 95% lower confidence limit and 95% upper confidence limit.

3.1.1.7. Article 7(a)(vii) The absence or presence and distribution of the disease in the Union, and, where the disease is not present in the Union, the risk of its introduction into the Union

Presence and distribution

Parameter 1 – Map where the disease is present in the European Union (EU) (Figure 2)

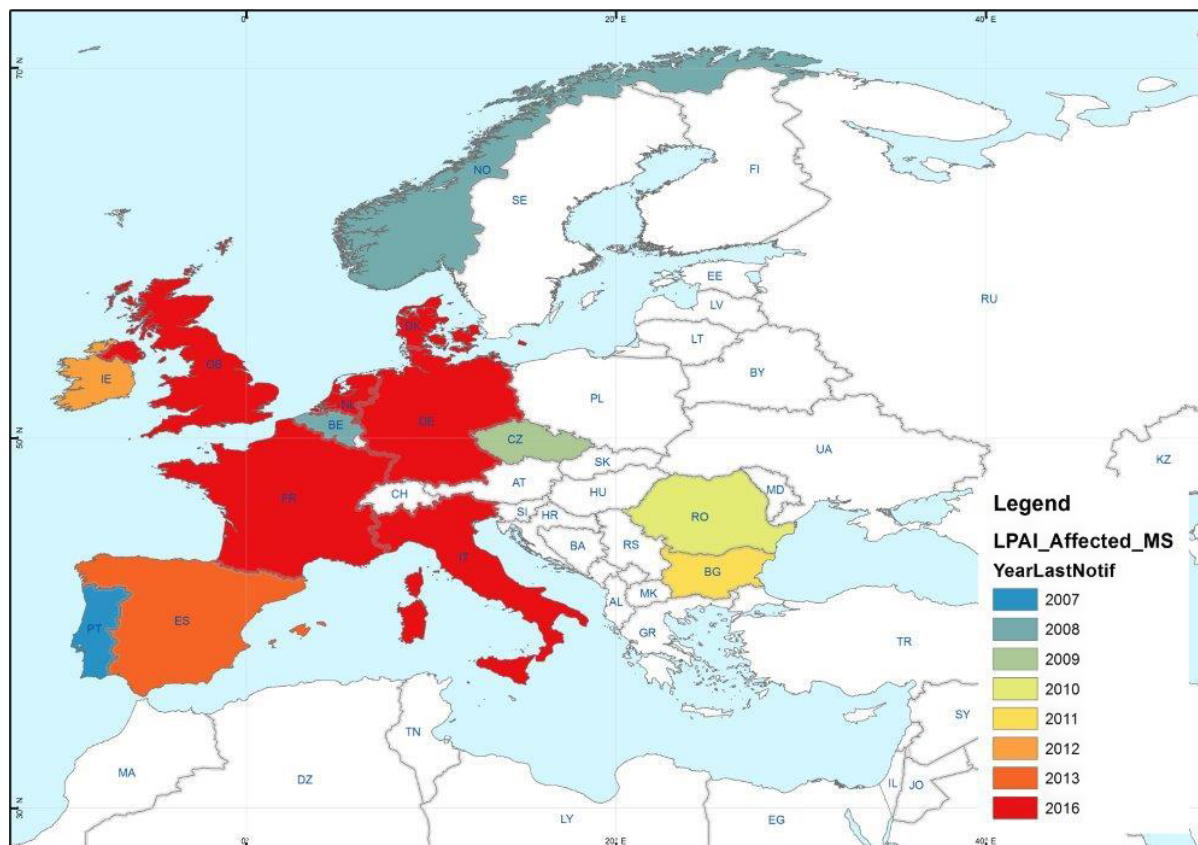


Figure 2: H5 and H7 LPAI outbreaks in poultry holdings and captive birds reported in ADNS between 2007 and 2016

Parameter 2 – Type of epidemiological occurrence (sporadic, epidemic, endemic) at MS level

In the MS that reported LPAI outbreaks in the last 10 years, some had very few outbreaks (e.g. only in a period of one or two years), whereas others reported outbreaks every year (see Table 5). In some cases, the sporadic outbreaks lead to wider epidemics, e.g. H7N7 Germany 2011 (Probst et al., 2012), H7N1 Italy 1999–2000 (Capua et al., 2002).

Risk of introduction

Parameter 3 – Routes of possible introduction

The disease could be introduced by several routes (EFSA, 2008):

- 1) Introduced by migration of wild birds. Infected migratory and indigenous wild birds are the most likely source of the virus for poultry in the EU. Direct contact with secretions and excretions, especially faeces, and possibly aerosol transmission from infected birds over short (few metres) distances (Jonges et al., 2015). At-risk matrices are contaminated feed, water, premises, human clothing, etc.

Usually by the introduction of infective faeces, e.g. on boots, clothing, vehicles, egg trays, birds cages or other fomites (feed and water contaminated by infective faeces have been shown to be responsible for introduction).

2) Outbreak of disease in a territory of a trading partner and infected birds or contaminated products imported that then may infect local birds:

- high risk with import of live affected birds;
- negligible risk with import of commodities or meat (Zepeda and Salman, 2007; Cobb, 2011);
- very low risk with import of eggs and egg products, providing eggs are sanitised (Cobb, 2011; Post et al., 2013; OIE, 2017).

There may be a risk if live birds are imported from affected countries where infection has been acquired after certification on premises of origin. Although this is considered a low probability event, for example the mean annual probability for HPAI introduction into Poland by legal trade was considered to be one outbreak in every 326 years (Gierak et al., 2016).

3) Illegal importation of birds from areas where disease is present.

Parameter 4 – Number of animal moving and/or shipment size

It was not possible to source reliable data within the time frame of this mandate. An overview will be provided in the scientific opinion on avian influenza that is scheduled for adoption in September 2017.

Parameter 5 – Duration of infectious period in animal and/or commodity

The duration of the infectious period in animals is described under parameter 1 of Article 7(a)(v) (see Section 3.1.1.5). The risk related to commodities is mainly due to contamination with (faecal) excretions. Survival of LPAIV will depend on temperature, humidity and pH as described under parameter 4 of Article 7(a)(v) (see Section 3.1.1.5).

Parameter 6 – List of control measures at border (testing, quarantine, etc.)

Legislation on imports of live poultry, day-old chicks and hatching eggs, table eggs, egg products and the meat of game birds and poultry is laid down in Regulation (EC) No 798/2008². This includes a list of approved countries for which there are certificates to allow the import of such consignments. Some countries are regionalised, some have special additional measures.

Once the consignments are imported into the EU, the Regulation requires that the birds be kept at the destination for a minimum of 3 weeks with sampling and (negative) testing for AI, during which time there is also monitoring for clinical signs.

The OIE Terrestrial Code chapter 10.4 (2010) describes the recommendations for importation of live birds other than poultry. In essence, regardless of the avian influenza status of the country of origin, an international veterinary certificate is required, attesting: (i) that the birds showed no clinical sign of avian influenza infection at the day of shipment, (ii) that the birds were kept in isolation since they were hatched or for at least 21 days prior to shipment and showed no clinical signs of avian influenza, (iii) that a statistically valid sample of the birds was tested to demonstrate freedom from avian influenza infection, (iv) that the birds are transported in new or appropriately sanitised containers.

EU rules are in place for the movement of pet birds (i.e. accompanied by their owner) or birds which are destined for special breeding programmes or for Approved Bodies (Council Directive 92/65/EEC³) into the Union.

Import into the EU of poultry meat is according to Regulation (EC) 798/2011. It is allowed to trade poultry meat from a country, zone or compartment affected by LPAI if the animals did not show any sign suggestive of AI infection during *ante* and *post mortem* inspection.

For the importation of egg products of poultry, regardless of the AI status of the country of origin, the commodity fulfils the requirements for importation of eggs for human consumption or the commodity has been processed to ensure the destruction of AI (heat inactivation achieving a 7-log reduction of AI, see OIE Code Article 10.4.25 for technical information) and contact with any source of AIV is prevented.

² Regulation (EC) No 798/2008 of the European Parliament and of the Council of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements. OJ L 226, 23.8.2008, p. 1–94.

³ Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC. OJ L 268, 14.9.1992, p. 54–72.

For imports into the Union of feathers and down, Regulation (EC) No 142/2011⁴ applies, requiring a prohibition on the import of untreated feather or down, while treated feathers and down (hot steam at 100°C for 30 min) may be placed on the market with no restrictions.

A list of control measures implemented in third countries or at the EU border related to import of live birds and commodities is provided in Table 9.

Table 9: List of control measures at the border related to import of live birds and commodities

Item	Measure
Live birds	Pre-inspection at origin, certification, veterinary inspection
Hatching eggs	Pre-inspection at origin, certification, veterinary inspection
Day-old chicks	Pre-inspection at origin, certification, veterinary inspection
Animal products	Certification, third country inspections for assurance (as required)
Captive birds	Certification, quarantine, testing

Parameter 7 – Presence and duration of latent infection and/or carrier status

See Section 3.1.1.5.

3.1.1.8. Article 7(a)(viii) The existence of diagnostic and disease control tools

Diagnostic tools

Parameter 1 – Existence of diagnostic tools

The avian influenza diagnostic tools are described in the Commission Decision 2006/437/EC⁵. In addition, there are specified laboratory manuals in the EU, Regulation (EC) No 2006/437⁶ applies, and at global level (OIE, 2017). Polymerase chain reaction (PCR) is used to determine the presence of LPAIV in suspected samples of live animals, commodities or environmental samples. The sensitivity and specificity varies depending on the virus subtype and the analysed matrix. Virus isolation is required for detailed analysis of a virus and is done with one or a few isolates per outbreak or epidemic. Sequencing is used to analyse the relation with other circulating viruses. The intravenous pathogenicity test (IVPI) is used to determine the pathogenicity level of a virus. Haemagglutination inhibition (HI) and enzyme-linked immunosorbent assay (ELISA) are used in seroprevalence studies. An overview of the available tools is provided in Table 10.

Table 10: Overview of AI diagnostic tools

Method	Test performance		Purpose				Sample type	Reference
	Dse	Dsp	Population freedom	Animal freedom	Disease confirmation	Surveillance inc post vacc		
Detection/ culture Virus isolation*			+	+++	+++	+	Tissues C&O swabs	(Commission Decision 2006/437/EC)
PCR (real-time) ¹	NK	NK	NK	NK	NK	NK	Tissues C&O swabs	(Commission Decision 2006/437/EC)

⁴ Regulation (EC) No 142/2011 of the European Parliament and of the Council of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive. OJ L 54, 26.2.2011, p. 1–254.

⁵ Commission Decision of 4 August 2006 approving a Diagnostic Manual for avian influenza as provided for in Council Directive 2005/94/EC. OJ L 237, 31.8.2006, p. 1–27.

⁶ Regulation (EC) No 2006/437 of the European Commission of 4 August 2006 approving a diagnostic manual for avian influenza as provided for in Council Directive 2005/94/EC. OJ L 237, 31.8.2006, p. 1–27.

Method	Test performance		Purpose				Sample type	Reference
	Dse	Dsp	Population freedom	Animal freedom	Disease confirmation	Surveillance inc post vacc		
Influenza A	NK	NK	++	+++	+++	++	Tissues C&O swabs	(Commission Decision 2006/437/EC; Slomka et al., 2010)
H5	100%	–	++	+++	+++	++	Tissues C&O swabs	(Commission Decision 2006/437/EC; Slomka et al., 2007)
H7	100%	90%	++	+++	+++	++	Tissues C&O swabs	(Commission Decision 2006/437/EC; Slomka et al., 2009)
Immune response HI	–	–	+++	++	++ convalescent	+++	Serum	(Commission Decision 2006/437/EC)
ELISA	NK	NK	+	+	+ convalescent	++	Serum	(Marche and van den Berg, 2010; OIE, 2017)
Virus characterisation gene sequencing	NK	100%	–	–	+++	–	Tissue / swab or virus	(OIE, 2017)
IVPI	–	–	–	–	+++	–	Virus	(OIE, 2017)

C&O swabs: cloacal and oropharyngeal swabs.

NK: not known; HI, haemagglutination inhibition test; IVPI, intravenous pathogenicity index.

*Gold standard but proven to be less sensitive and furthermore, real-time PCR reactors specific from known population.

¹Sensitivity (Dse) and specificity (Dsp) values measured against virus isolation.

Control tools

Parameter 2 – Existence of control tools

The control measures for avian influenza mainly aim to prevent virus spread to other poultry holdings. The measures are described in Council Directive 2005/94/EC⁷ and an overview is presented in Table 11. In case of a LPAI outbreak, the competent authority shall immediately establish a restricted zone with a radius of at least 1 km around the holding. An inventory is made of the animals present on the affected holding and the animals should be brought and kept inside. No carcasses, meat, animal by-products, manure, slurry used litter or anything likely to transmit LPAIV may leave the holding without authorisation. Furthermore, an epidemiological investigation is performed. Holdings in which infection with LPAIV has been confirmed are depopulated, followed by cleaning and disinfection of the houses and equipment. Poultry and eggs cannot be moved until the risk of LPAI spread is determined as minimal. Hatching eggs are put under surveillance. Persons entering or leaving the holding and transport vehicles have to follow specific biosecurity requirements aiming to prevent the spread of the virus. Preventive or emergency vaccination is possible although only used in few cases⁸ (e.g. in Italy between 2000 and 2008 and in Portugal between 2007 and 2011) (Capua and Marangon, 2006). Repopulation is done in a controlled manner.

⁷ Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC. OJ L 10, 14.1.2006, p. 16-65.

⁸ https://ec.europa.eu/food/animals/animal-diseases/control-measures/avian-influenza_en

Table 11: Available control measures for avian influenza

Measure	Application
Farm restrictions	Live birds, hatching eggs, meat, animal by-products, table eggs, equipment, vehicles, people, slurry/manure, litter
Zoning/quarantine/surveillance	1 km protection zone, farm census/inspection, laboratory testing of farms
Movement restrictions	Live birds, hatching eggs, meat, animal by-products, table eggs
Culling and disposal	Infected farm
Biosecurity	Specified requirements
Transport	Specified requirements
Epidemiological enquiry	Determine spread, identify source
Cleansing and disinfection	Specified requirements
Vaccination	Exceptional use
Repopulation	Controlled

3.1.2. Article 7(b) The impact of diseases

3.1.2.1. Article 7(b)(i) The impact of the disease on agricultural and aquaculture production and other parts of the economy

The level of presence of the disease in the Union

Parameter 1 – Number of MSs where the disease is present

In the period 2007–2016, LPAI outbreaks were reported in 14 MS through ADNS (see Table 5). The number of outbreaks per year ranged from 9 to 57 and reached a total of 321 in these 10 years.

The loss of production due to the disease

Parameter 2 – Proportion of production losses (%) by epidemic/endemic situation

Morbidity and mortality of LPAI in poultry is limited, as described in Section 3.1.1.2. The main loss due to LPAI is the depopulation of affected holdings. In the period 2007–2016, 1.7×10^6 poultry were culled within the EU (see Table 12). Additional losses are related to movement restrictions, which lead to economic loss of table eggs, hatching eggs and live animals. Indirect costs are for instance trade bans to third countries, treatment and removal of manure and wash water, closing of processing plants. The estimated total economic cost of the LPAI epidemic in Italy in 1999 was about 507 million euro (112 and 395 million euro direct and indirect costs respectively) (Sartore et al., 2010). The total cost for five subsequent LPAI outbreaks in Italy was estimated around 143 million euro.

Table 12: Overview of diseased, dead and culled poultry due to LPAI outbreaks reported in ADNS between 2007 and 2016

	Diseased poultry	Dead poultry	Culled poultry	Grand total
2007	31,776	3,491	126,398	161,665
2008	452	8,199	358,724	367,375
2009	355	572	176,327	177,254
2010	2,093	1	55,527	57,621
2011	51,955	201	308,457	360,613
2012	103,390	148	221,970	325,508
2013	11,973	135	135,689	147,797
2014	186	50	50,300	50,536
2015	11,282	152	69,767	81,201
2016	236	5	21,568	21,809
Grand total	213,698	12,954	1,524,727	1,751,379

LPAI: low pathogenic avian influenza.

3.1.2.2. Article 7(b)(ii) The impact of the disease on human health

Transmissibility between animals and humans

Parameter 1 – Types of routes of transmission between animals and humans

Avian influenza viruses do not readily infect people, but can do so when people have close contact with infected birds or exposure to high viral loads in untreated products. The illness caused by avian influenza viruses can present itself as a flu-like respiratory illness or conjunctivitis (Kim et al., 2016).

Parameter 2 - Incidence of zoonotic cases

With increased awareness that AI viruses can infect humans, investigations of human contacts during poultry outbreaks with LPAI have detected a small number of human cases. Poor transmissibility to humans with most LPAIV has been reported with only four human cases reported in Europe (Kim et al., 2016; Table 4). One exception is an H7N9 LPAIV confined to China that has caused 1,157 human cases since 2013 with approximately 30% mortality (WHO, 2015). The composition of this virus is entirely distinct from viruses circulating in European poultry and wild birds.

Transmissibility between humans

Parameter 3 – Human to human transmission is sufficient to sustain sporadic cases or community-level outbreak

LPAIV lacks human to human transmissibility.

Parameter 4 – Sporadic, endemic, epidemic or pandemic potential

Only four human cases have been reported in Europe, nonetheless, there is theoretical pandemic potential.

The availability of effective prevention or medical treatment in humans

Parameter 6 – Availability of medical treatment and their effectiveness (therapeutic effect and any resistance)

Antiviral drugs are available but some levels of resistance are reported. These drugs are effective only if taken early in the infection course (Loregian et al., 2014).

Parameter 7 – Availability of vaccines and their effectiveness (reduced morbidity)

Vaccines are not routinely available for human application. WHO has pre-pandemic vaccine stock containing some LPAIV strains for rapid production, if a pandemic were to emerge from an LPAI virus (WHO, 2015).

3.1.2.3. Article 7(b)(iii) The impact of the disease on animal welfare

Parameter 1 – Severity of clinical signs at case level and related level and duration of impairment

Clinical signs, as defined above, are usually very mild, i.e. laying birds going out of lay so the impact is very low unless exacerbated by secondary infections. Low levels of mortality can occur in susceptible species.

3.1.2.4. Article 7(b)(iv) The impact of the disease on biodiversity and the environment

Biodiversity

Parameter 1 – Endangered wild species affected: listed species as in CITES and/or IUCN list

Not applicable as LPAI in wild species is usually asymptomatic.

Environment

Parameter 3 – Capacity of the pathogen to persist in the environment and cause mortality in wildlife

While the pathogen can survive in the environment, it presents no risk to wildlife in terms of mortality.

3.1.3. Article 7(c) Its potential to generate a crisis situation and its potential use in bioterrorism

Parameter 1 – Listed in OIE/CFSPH classification of pathogens

It is listed.

Parameter 2 – Listed in the *Encyclopaedia of Bioterrorism Defence of Australia Group*

It is not listed.

Parameter 3 – Included in any other list of potential bio-agroterrorism agents

It is not listed.

3.1.4. Article 7(d) The feasibility, availability and effectiveness of the following disease prevention and control measures

3.1.4.1. Article 7(d)(i) Diagnostic tools and capacities

See Section 3.1.1.8 and Table 10 which provides summary data for all three aspects.

3.1.4.2. Article 7(d)(ii) Vaccination

There are five vaccines available for LPAI in poultry, which reduce viral shedding. The duration of protection varies from 14 weeks to 12 months in chicken and 14 weeks in ducks. All vaccines comply to the DIVA principle, as required by the EU legislation. Table 13 (FAO, 2009; EMA, 2010; Discontools, 2016) provides an overview of the vaccine characteristics (Marangon et al., 2003; Busani et al., 2007; Capua et al., 2009; Beato et al., 2014).

Table 13: LPAI vaccine availability and effectiveness¹

Vaccine	Type/ administration	Effectiveness	Field protection	Duration of protection	Diva	Availability/ production capacity*
Nobilis flu H5N2 ²	Inactivated IM and SC	Reduced clinical signs and viral shedding	n/a	12 months in chicken	Y ³	Y Capacity unknown
Nobilis flu H7N1/ H7N7	Inactivated IM and SC	Reduced clinical signs and viral shedding	Italy 2002–2003 R ₀ 2.9 pre-vaccination to 0.6 post-vaccination	45 weeks	Y ³	Y Capacity unknown
Poulvac Flu-Fend H5N3	Inactivated IM and SC	Reduced clinical signs and viral shedding	n/a	14 weeks in ducks	Y ³	Y Capacity unknown
Merial Trovac H5	Vectored HA insert SC	Reduced clinical signs and viral shedding	n/a	20 weeks in chicken	Y	Y Capacity unknown
Gallimune H5N9 or H7N1	Inactivated IM and SC	Reduced clinical signs and viral shedding	n/a	Not known	Y ³	Y Capacity unknown

SC: subcutaneous; IM: intramuscular.

¹Note this is not an exhaustive list of vaccines, but it indicates some vaccines historically used in the EU.

²EMA authorisation.

³Companion diagnostics not on the shelf.

*Commercial suppliers tailor supply to demand.

Feasibility

Parameter 5 – Way of administration

Vaccinations by commercially available vaccines are carried out by injection (IM or SC).

3.1.4.3. Article 7(d)(iii) Medical treatments

Antiviral drugs are prohibited for application in the veterinary sector and therefore this section is not applicable.

3.1.4.4. Article 7(d)(iv) Biosecurity measures

Availability

Parameter 1 – Available biosecurity measures

Procedures or practices that prevent or limit exposure to LPAIV include farm hygiene, environmental control, medication to prevent secondary challenge and effective sanitation. Key elements are farm location to mitigate risk for introduction, farm design, access control of people and vehicles, sanitation of materials entering and leaving the site including equipment, litter, vermin control, limiting access to wild birds or their faeces when birds are kept outdoors, water sanitation, physical barriers to poultry house, including boot changes and protective clothing, quarantine new stock, exclude access of wild birds to feed and litter disposal (Lister, 2008; EFSA AHAW Panel, 2017a,b).

Effectiveness

Parameter 2 – Effectiveness of biosecurity measures in preventing the pathogen introduction

A combination of factors will provide effective biosecurity, but key elements include limiting access for wild birds and reducing fomite transmission risk through effective sanitisation when entering into poultry houses. In some systems, mitigation of access to wild bird or their faeces, e.g. in outdoor system can be achieved by ensuring that feed is not readily accessible or by limiting the access to outdoor range by wild birds (by nets or fences). Appropriate management to monitor changes in production and flock health are critical for prompt awareness of early indicators of infection, i.e. more than 20% reduction in feed or water intake or more than 5% of egg drop for more than 2 days in laying birds (Annex II to Decision 2005/734/EC). Implementation of biosecurity measures is key to disease prevention/control (Gonzales et al., 2014).

Feasibility

Parameter 3 – Feasibility of biosecurity measure

In large-scale integrated commercial operations, biosecurity programmes are a usual part of business. However, in other production systems, such as outdoor rearing, implementation of biosecurity measures is more challenging and only limited elements in practice can be applied. The introduction of LPAIV almost always can be attributed to failures in application of biosecurity measures or direct contact with wild birds or their faeces. In reality, when the disease threat is perceived to increase, measures are strengthened but may be relaxed in lower risk periods.

3.1.4.5. Article 7(d)(v) Restrictions on the movement of animals and products

Availability

Parameter 1 – Available movement restriction measures

See Table 11, Section 3.1.1.8.

Effectiveness

Parameter 2 – Effectiveness of restriction of animal movement in preventing the between farm spread

Proven in EU; when applied promptly and coupled with early reporting, disease spread is mitigated. Between-farm spread of LPAI is generally low in the absence of control measures, dependent on the species, e.g. duck sector.

Feasibility

Parameter 3 – Feasibility of restriction of animal movement

Appropriate veterinary infrastructure is in place in the MSs to comply. The implementation of movement restrictions is feasible because risk-based derogations are permitted.

3.1.4.6. Article 7(d)(vi) Killing of animals

Availability

Parameter 1 – Available methods for killing animals

Controlled through Regulation (EC) No 1099/2009⁹ under which the Competent Authority can derogate the method of killing 'where it considers that compliance is likely to affect human health or significantly slow down the process of eradication of a disease'. Multiple methods are available principally on site to include gassing in containers and use of anoxic foam on site or through safe transport to slaughterhouse where a veterinary risk assessment deems the risk of spreading the virus to be very low. LPAI killed birds, provided that they are properly labelled, are fit for entering the food chain.

Effectiveness

Parameter 2 – Effectiveness of killing animals (at farm level or within the farm) for reducing/stopping spread of the disease

It is highly effective to kill animals on site, and mitigating the risk for transport of animals away from infected premise contributes to reducing or stopping disease spread, which needs to be done in a controlled environment to avoid aerosols and local windborne spread of virus. Attention has to be paid to secure the transportation of dead animals.

Feasibility

Parameter 3 – Feasibility of killing animals

Logistical challenges and R_0 values will depend on speed of slaughter; to reduce risk for a fast-spreading outbreak-infected flocks must be culled quickly, ideally within 48 hours of diagnosis. Logistical challenges in some operational settings, such as outdoor production, where for moderately small (juvenile) populations manual neck dislocation is an option. Contingency plans are required under Regulation (EC) No 1099/2009. These plans need to factor in animal welfare (humane culling methods), public health risk (by not killing out fast and use methods to reduce exposure) and personnel safety, practicality of measures applied and speed and all should be under official veterinary supervision.

3.1.4.7. Article 7(d)(vii) Disposal of carcasses and other relevant animal by-products

Availability

Parameter 1 – Available disposal option

Disposal options for poultry carcasses and associated wastes are: commercial fixed plant incineration, rendering (category 1 and 2 Animal By-Product Regulation approved), permitted commercial landfill sites.

Effectiveness

Parameter 2 – Effectiveness of disposal option

Incineration and rendering are closed systems that produce an effective inactivation of LPAIV. Landfill may not inactivate all pathogens but could be used only for non-infected carcasses.

Feasibility

Parameter 3 – Feasibility of disposal option

Operational protocols for use of incineration, rendering and permitted landfill have been successfully utilised in a number of exotic avian disease outbreaks.

⁹ Regulation (EC) No 1099/2009 of the European Parliament and of the Council of 24 September 2009 on the protection of animals at the time of killing. OJ L 303, 18.11.2009, p. 1–30.

3.1.5. Article 7(e) The impact of disease prevention and control measures

3.1.5.1. Article 7(e)(i) The direct and indirect costs for the affected sectors and the economy as a whole

Parameter 1 – Cost of control (e.g. treatment/vaccine, biosecurity)

This is difficult to quantify, but significant costs are linked with the implementation of biosecurity. Nevertheless, the industry would need to deploy for good practice regardless of LPAI threat.

Parameter 2 – Cost of eradication (culling, compensation)

The economic burden for five successive LPAI epidemics in Italy was estimated €143 million (€105 million in direct losses and €38 million in consequential losses) (Sartore et al., 2010). There were no other data identified regarding LPAI culling and/or compensation. Eradication of LPAI is not an objective.

Parameter 3 – Cost of surveillance and monitoring

Since 2003, MS have the obligation (Council Directive 2005/94/EC) to carry out surveillance programmes in poultry aiming to detect LPAI H5 and H7 viruses which have the potential to mutate to HPAI. Based on MS' programmes submitted for EU co-financing, a cost of approximately €4.3 million per annum is estimated (based on last 3 years). The cost of a surveillance programme is also dependent on its design (Rutten et al., 2012). LPAI surveillance in wild birds is not performed.

Parameter 4 – Trade loss (bans, embargoes, sanctions) by animal product

Information not logged with Commission services. No relevant data could be identified.

Parameter 5 – Importance of the disease for the affected sector (% loss or euro lost compared to business amount of the sector)

It is difficult to estimate the loss for the sector in the EU since the loss is different between MS and one needs to differentiate between the trade in hatching eggs and day-old chicks that may be differentiated too as there are chicks at different stages from great grandparent, parent and broiler.

3.1.5.2. Article 7(e)(ii) The societal acceptance of disease prevention and control measures

There is little information on case studies relating to LPAI more conversely with HPAI, however, culling of affected flocks raises societal issues and a perceived lack of vaccination to control. In an EU context, there are very limited episodes of extensive LPAI spread and these primarily occurred before formal notification and control tools were implemented. Some pressure has come from welfare sectors to quarantine infected birds until infection is resolved. Possibilities do exist, but the rationale for control of LPAI by culling is to reduce risk of virus mutation to the more impactful HPAI.

3.1.5.3. Article 7(e)(iii) The welfare of affected subpopulations of kept and wild animals

Parameter 1 – Welfare impact of control measures on domestic animals

For every outbreak, an assessment will be made when putting restrictions in place that will consider animal welfare implications; where animal welfare is compromised, and there is no alternative, culling will be considered as a mechanism to prevent animal suffering. Movement restriction can lead to overcrowding, i.e. broilers but derogations are available to alleviate this on welfare grounds without overt disease risk. As part of the mechanism to set up biosecurity measures EU MS's factor animal welfare considerations, i.e. confining some ducks indoors is unacceptable and options exist to permit some outdoor access by use of netting (OIE, 2017).

Parameter 2 – Wildlife depopulation as control measure

It is not practised.

3.1.5.4. Article 7(e)(iv) The environment and biodiversity

Environment

Parameter 1 – Use and potential residuals of biocides or medical drugs in environmental compartments (soil, water, feed, manure)

They are not used.

Biodiversity

Parameter 2 – Mortality in wild species

LPAI infections do not generally cause major clinical signs, nor do they cause mortality in wild birds (Ferreira et al., 2010; Bertran et al., 2012; Kuiken, 2013).

3.2. Assessment according to Article 5 criteria

This section presents the results of the expert judgement on the criteria of Article 5 of the AHL about LPAI (Table 14). The expert judgement was based on Individual and Collective Behavioural Aggregation (ICBA) approach described in detail in the opinion on the methodology (EFSA AHAW Panel, 2017a,b). Experts have been provided with information of the disease factsheet mapped into Article 5 criteria (see supporting information, Annex A), based on that the experts indicate their Y/N or 'na' judgement on each criterion of Article 5, and the reasoning supporting their judgement. As from the legal text of the AHL, a disease is considered eligible to be listed as laid down in Article 5 if it fulfils all criteria of the first set from A(i) to A(v) and at least one of the second set of criteria from B(i) to B(v). According to the assessment methodology (EFSA AHAW Panel, 2017a,b), a criterion is considered fulfilled when the outcome is 'Yes'.

The minimum number of judges in the judgement was 10. The expert judgement was conducted as described in the methodological opinion (EFSA AHAW Panel, 2017a,b). For details on the interpretation of the questions, see Appendix B of the methodological opinion (EFSA AHAW Panel, 2017a,b).

Table 14: Outcome of the expert judgement on the Article 5 criteria for LPAI

Criteria to be met by the disease:		Final outcome
According to AHL, a disease shall be included in the list referred to in point (b) of paragraph 1 of Article 5 if it has been assessed in accordance with Article 7 and meets all of the following criteria		
A(i)	The disease is transmissible	Y
A(ii)	Animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union	Y
A(iii)	The disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character	Y
A(iv)	Diagnostic tools are available for the disease	Y
A(v)	Risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union	Y
At least one criterion to be met by the disease:		
In addition to the criteria set out above at point A(i)–A(v), the disease needs to fulfil at least one of the following criteria		
B(i)	The disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character	Y
B(ii)	The disease agent has developed resistance to treatments and poses a significant danger to public and/or animal health in the Union	NC
B(iii)	The disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union	Y
B(iv)	The disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism	N
B(v)	The disease has or could have a significant negative impact on the environment, including biodiversity, of the Union	N

Colour code: green = consensus (Yes/No); yellow = no consensus (NC)

3.2.1. Non-consensus questions

This section displays the assessment related to each criterion of Article 5 where no consensus was achieved in form of tables (Table 15). The proportion of Y, N or na answers are reported, followed by the list of different supporting views for each answer.

Table 15: Outcome of the expert judgement related to criterion 5 B(ii)

Question		Final outcome	Response		
			Y (%)	N (%)	na (%)
B(ii)	The disease agent has developed resistance to treatments and poses a significant danger to public and/or animal health in the Union	NC	30	70	0

NC: non-consensus; number of judges: 10.

Reasoning supporting the judgement

supporting yes:

- It is entirely plausible that resistance will increase, posing increasing dangers to public and/or animal health, extrapolating from broader AMR experiences, problems of resistance will increase.
- Resistance has been demonstrated in humans.
- The illegal use of antivirals could possibly cause resistance.
- Resistance has been demonstrated in Egypt and China.

supporting no:

- Resistance occurrence has been reported on two occasions with probable re-assortment, but this seems not relevant for the EU.
- Possible resistance does not pose a significant danger to public health because symptoms in humans are usually mild and often not treated.
- There is no treatment in poultry in the EU. It is not indicated and too expensive.
- Resistance has only been described in human strains.

3.2.2. Outcome of the assessment of LPAI according to criteria of Article 5(3) of the AHL on its eligibility to be listed

As from the legal text of the AHL, a disease is considered eligible to be listed as laid down in Article 5 if it fulfils all criteria of the first set from A(i) to A(v) and at least one of the second set of criteria from B(i) to B(v). According to the assessment methodology (EFSA AHAW Panel, 2017a,b), a criterion is considered fulfilled when the outcome is 'yes'. According to the results shown in Table 14, LPAI complies with all criteria of the first set and with two criteria of the second set, therefore it is considered eligible to be listed as laid down in Article 5 of the AHL.

3.3. Assessment according to Article 9 criteria

This section presents the results of the expert judgement on the criteria of Annex IV referring to categories as in Article 9 of the AHL about LPAI (Tables 16–20). The expert judgement was based on ICBA approach described in detail in the opinion on the methodology. Experts have been provided with information of the disease factsheet mapped into Article 9 criteria (see supporting information, Annex A), based on that the experts indicate their Y/N or 'na' judgement on each criterion of Article 9, and the reasoning supporting their judgement. The minimum number of judges in the judgement was 10. The expert judgement was conducted as described in the methodological opinion (EFSA AHAW Panel, 2017a,b). For details on the interpretation of the questions, see Appendix B of the methodological opinion (EFSA AHAW Panel, 2017a,b).

Table 16: Outcome of the expert judgement related to the criteria of section 1 of Annex IV (category A of Article 9) for LPAI (CI = current impact; PI = potential impact)

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		Final outcome
1	The disease is not present in the territory of the Union OR present only in exceptional cases (irregular introductions) OR present in only in a very limited part of the territory of the Union	N
2.1	The disease is highly transmissible	N
2.2	There be possibilities of airborne or waterborne or vector-borne spread	Y
2.3	The disease affects multiple species of kept and wild animals OR single species of kept animals of economic importance	Y
2.4	The disease may result in high morbidity and significant mortality rates	N
At least one criterion to be met by the disease: In addition to the criteria set out above at point 1–2.4, the disease needs to fulfil at least one of the following criteria		
3	The disease has a zoonotic potential with significant consequences on public health, including epidemic or pandemic potential OR possible significant threats to food safety	N
4(CI)	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	N
4(PI)	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	N
5(a)(CI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(a)(PI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	N
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(d)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No)

Table 17: Outcome of the expert judgement related to the criteria of section 2 of Annex IV (category B of Article 9) for LPAI (CI = current impact; PI = potential impact)

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		Final outcome
1	The disease is present in the whole OR part of the Union territory with an endemic character AND (at the same time) several Member States or zones of the Union are free of the disease	N
2.1	The disease is moderately to highly transmissible	Y
2.2	There be possibilities of airborne or waterborne or vector-borne spread	Y
2.3	The disease affects single or multiple species	Y
2.4	The disease may result in high morbidity with in general low mortality	Y
At least one criterion to be met by the disease: In addition to the criteria set out above at point 1–2.4, the disease needs to fulfil at least one of the following criteria		
3	The disease has a zoonotic potential with significant consequences on public health, including epidemic potential OR possible significant threats to food safety	N
4(CI)	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	N
4(PI)	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	N

5(a)(CI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(a)(PI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	N
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(d)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No)

Table 18: Outcome of the expert judgement related to the criteria of section 3 of Annex IV (category C of Article 9) for LPAI (CI = current impact; PI = potential impact)

Criteria to be met by the disease:		Final outcome
The disease needs to fulfil all of the following criteria		
1	The disease is present in the whole OR part of the Union territory with an endemic character	Y
2.1	The disease is moderately to highly transmissible	Y
2.2	The disease is transmitted mainly by direct or indirect transmission	Y
2.3	The disease affects single or multiple species	Y
2.4	The disease usually does not result in high morbidity and has negligible or no mortality AND often the most observed effect of the disease is production loss	Y

At least one criterion to be met by the disease:

In addition to the criteria set out above at point 1–2.4, the disease needs to fulfil at least one of the following criteria

3	The disease has a zoonotic potential with significant consequences on public health, or possible significant threats to food safety	N
4(CI)	The disease has a significant impact on the economy of the Union, mainly related to its direct impact on certain types of animal production systems	N
4(PI)	The disease has a significant impact on the economy of the Union, mainly related to its direct impact on certain types of animal production systems	Y
5(a)(CI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(a)(PI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	N
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(d)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No)

Table 19: Outcome of the expert judgement related to the criteria of section 4 of Annex IV (category D of Article 9) for LPAI

Criteria to be met by the disease:		Final outcome
The disease needs to fulfil all of the following criteria		
D	The risk posed by the disease in question can be effectively and proportionately mitigated by measures concerning movements of animals and products in order to prevent or limit its occurrence and spread	N
Criteria of section 1, 2, 3 or 5 of Annex IV of AHL		Y

Colour code: green = consensus (Yes/No)

Table 20: Outcome of the expert judgement related to the criteria of section 5 of Annex IV (category E of Article 9) for LPAI

Diseases in category E need to fulfil criteria of section 1, 2 or 3 of Annex IV of AHL and/or the following:		Final outcome
E	Surveillance of the disease is necessary for reasons relating to animal health, animal welfare, human health, the economy, society or the environment (If a disease fulfils the criteria as in Article 5, thus being eligible to be listed, consequently category E would apply.)	Y

Colour code: green = consensus (Yes/No)

3.3.1. Outcome of the assessment of criteria in Annex IV for LPAI for the purpose of categorisation as in Article 9 of the AHL

As from the legal text of the AHL, a disease is considered fitting in a certain category (A, B, C, D or E corresponding to point (a) to point (e) of Article 9(1) of the AHL) if it is eligible to be listed for Union intervention as laid down in Article 5(3) and fulfils all criteria of the first set from 1 to 2.4 and at least one of the second set of criteria from 3 to 5(d) as shown in Tables 16–20. According to the assessment methodology (EFSA AHAW Panel, 2017a,b), a criterion is considered fulfilled when the outcome is 'yes'. With respect to different type of impact where the assessment is divided into current and potential impact, a criterion will be considered fulfilled if at least one of the two outcomes is 'Y' and, in case of no 'Y', the assessment is inconclusive if at least one outcome is 'NC'.

A description of the outcome of the assessment of criteria in Annex IV for LPAI for the purpose of categorisation as in Article 9 of the AHL is presented in Table 21.

Table 21: Outcome of the assessment of criteria in Annex IV for LPAI for the purpose of categorisation as in Article 9 of the AHL (CI = current impact; PI = potential impact)

Category	Article 9 criteria										
	1° set of criteria					2° set of criteria					
	1	2.1	2.2	2.3	2.4	3	4	5a	5b	5c	5d
	Geographical distribution	Transmissibility	Routes of transmission	Multiple species	Morbidity and mortality	Zoonotic potential	Impact on economy	Impact on society	Impact on animal welfare	Impact on environment	Impact on biodiversity
A	N	N	Y	Y	N	N	N	N	N	N	N
B	N	Y	Y	Y	Y	N	N	N	N	N	N
C	Y	Y	Y	Y	Y	N	CI: N PI: Y	N	N	N	N
D	N										
E	Y										

According to the assessment here performed, LPAI complies with the following criteria of the sections 1 to 5 of Annex IV of the AHL for the application of the disease prevention and control rules referred to in points (a) to (e) of Article 9(1):

- 1) To be assigned to category A, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment LPAI complies with criteria 2.2 and 2.3 but does not comply with criteria 1, 2.1 and 2.4. To be eligible for category A, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and LPAI does not comply with any of them.
- 2) To be assigned to category B, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment LPAI complies with criteria 2.1, 2.2, 2.3 and 2.4 but does not comply with criterion 1. To be eligible for category A, a disease needs to

comply additionally with one of the criteria of the second set (3, 4, 5a–d) and LPAI does not comply with any of them.

- 3) To be assigned to category C, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment LPAI complies with all. To be eligible for category A, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and LPAI complies with criterion 4 and does not comply with criteria 3, 5a–5d.
- 4) To be assigned to category D, a disease needs to comply with criteria of section 1, 2, 3 or 5 of Annex IV of the AHL, which LPAI complies with, and with the specific criterion D of section 4, which LPAI does not comply with.
- 5) To be assigned to category E, a disease needs to comply with criteria of section 1, 2 or 3 of Annex IV of the AHL and/or the surveillance of the disease is necessary for reasons relating to animal health, animal welfare, human health, the economy, society or the environment. The latter is applicable if a disease fulfils the criteria as in Article 5, which LPAI complies with.

3.4. Assessment of Article 8

This section presents the results of the assessment on the criteria of Article 8(3) of the AHL about LPAI. The Article 8(3) criteria are about animal species to be listed, as it reads below:

'3. Animal species or groups of animal species shall be added to this list if they are affected or if they pose a risk for the spread of a specific listed disease because:

- a) they are susceptible for a specific listed disease or scientific evidence indicates that such susceptibility is likely; or
- b) they are vector species or reservoirs for that disease, or scientific evidence indicates that such role is likely.'

For this reason, the assessment on Article 8 criteria is based on the evidence as extrapolated from the relevant criteria of Article 7, i.e. the ones related to susceptible and reservoir species or routes of transmission, which cover also possible role of biological or mechanical vectors.¹⁰ According to the mapping, as presented in Table 5, section 3.2 of the scientific opinion on the ad hoc methodology (EFSA AHAW Panel, 2017b), the main animal species to be listed for LPAI according to the criteria of Article 8(3) of the AHL are as displayed in Table 22.

¹⁰ A vector is a living organism that transmits an infectious agent from an infected animal to a human or another animal. Vectors are frequently arthropods. Biological vectors may carry pathogens that can multiply within their bodies and be delivered to new hosts, usually by biting. In mechanical vectors the pathogens do not multiply within the vector, which usually remains infected for shorter time than in biological vectors.

Table 22: Animal species to be listed for LPAI according to criteria of Article 8 (source: data reported in Section 3.1.1.1)

	Class	Order	Family	Genus/Species
Susceptible	Aves	Anseriformes	Anatidae	<i>Cygnus olor</i> , <i>Anas platyrhynchos</i> , <i>Anas acuta</i> , <i>Anas clypeata</i> , <i>Branta canadensis</i> , <i>Cygnus columbianus</i> , <i>Anas americana</i> , <i>Anas sponsa</i> , <i>Anas albifrons</i> , <i>Anas crecca</i> , <i>Anas penelope</i> , <i>Anas querquedula</i> , <i>Anas strepera</i> , <i>Anser anser</i> , <i>Anser erythropus</i> , <i>Anser fabalis</i> , <i>Aythya ferina</i> , <i>Aythya fuligula</i> , <i>Chloephaga poliocephala</i> , <i>Cygnus cygnus</i> , <i>Histrionicus histrionicus</i> , <i>Oxyura jamaicensis</i> , <i>Tadorna tadorna</i>
				<i>Arenaria interpres</i> , <i>Gallinago gallinago</i>
				<i>Leucophaeus atricilla</i> , <i>Larus delawarensis</i> , <i>Larus ridibundus</i> , <i>Larus argentatus</i> , <i>Larus marinus</i>
				<i>Recurvirostra avosetta</i>
				<i>Fulica atra</i>
				<i>Nycticorax nycticorax</i>
				<i>Phalacrocorax carbo</i>
				<i>Gallus</i> spp., <i>Meleagris</i> spp., Phasianinae, <i>Coturnix</i> spp., <i>Anurophasis</i> spp., <i>Perdica</i> spp., <i>Ophrysia</i> spp.
				not specified
				not specified
				<i>Struthio</i> spp. and other ratites ^(a)
	Mammalia	Artiodactyla	Suidae	<i>Sus</i> spp.
				<i>Equus</i> spp.
		Carnivora	Canidae	<i>Canis</i> spp.
				<i>Felis catus</i>
			Mustelidae	Not specified
			Enaliarctidae	Not specified
		Rodentia	Muridae	<i>Mus</i> spp., <i>Rattus</i> spp.
				<i>Cavia porcellus</i>
		Primates	Not specified	

	Class	Order	Family	Genus/Species
Reservoir	Aves	Anseriformes	Not specified	
		Charadriiformes	Not specified	
Vectors	None			

(a): Sometimes classified as a diverse group of large, flightless birds of the infraclass Palaeognathae.

4. Conclusions

TOR 1: *for each of those diseases an assessment, following the criteria laid down in Article 7 of the AHL, on its eligibility of being listed for Union intervention as laid down in Article 5(3) of the AHL;*

- According to the assessment here performed, LPAI complies with all criteria of the first set and with two criteria of the second set and therefore can be considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL.

TOR 2a: *for each of the diseases which was found eligible to be listed for Union intervention, an assessment of its compliance with each of the criteria in Annex IV to the AHL for the purpose of categorisation of diseases in accordance with Article 9 of the AHL;*

- According to the assessment here performed, LPAI meets the criteria as in Sections 3 and 5 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in points (c) and (e) of Article 9(1) of the AHL.

TOR 2b: *for each of the diseases which was found eligible to be listed for Union intervention, a list of animal species that should be considered candidates for listing in accordance with Article 8 of the AHL.*

- According to the assessment here performed, the animal species that can be considered to be listed for LPAI according to Article 8(3) of the AHL are Anseriformes and Charadriiformes as well as all domestic poultry species (chicken, turkeys and related poultry such as quail, guinea fowl and pheasant, and ostriches) as susceptible species, and mainly Anseriformes and Charadriiformes as reservoir species, as reported in Table 22 in Section 3.4 of the present document.

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Abbreviations

AI	avian influenza
AHL	Animal Health Law
ELISA	enzyme-linked immunosorbent assay
HI	Haemagglutination inhibition
HPAI	highly pathogenic avian influenza
HPAIV	highly pathogenic avian influenza virus
ICBA	individual and Collective Behavioural Aggregation
IM	intramuscular
IVPI	intravenous pathogenicity test
LPAI	low pathogenic avian influenza
LPAIV	low pathogenic avian influenza virus
PCR	polymerase chain reaction
ToR	Terms of Reference
C&O swabs	Cloacal and oropharyngeal swabs
SC	Subcutaneous